IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
Nashville Division

L.W., by and through her parents and next friends, Samantha Williams and Brian Williams, *et al.*, *Plaintiffs*, *v.* JONATHAN SKRMETTI, in his official capacity as the Tennessee Attorney General and Reporter, *et al.*, *Defendants.*	Civil No. 3:23-cv-00376

EXPERT DECLARATION OF
ARMAND H. MATHENY ANTOMMARIA, MD, PhD, FAAP, HEC-C

I, Armand H. Matheny Antommaria, hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I have actual knowledge of the matters stated herein.

3. In preparing this declaration, I reviewed Tennessee Senate Bill 1 (hereafter "the ban"). In addition to this legislation and the materials cited herein, I have also relied on my years of research and other experience, as set out in my curriculum vitae (Exhibit A), in forming my opinions. The materials I have relied upon in preparing this declaration are the same types of materials that experts in my fields of study regularly rely upon when forming opinions on subjects. I may wish to supplement these opinions or the bases for them as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

OVERVIEW

4. I am a pediatrician and bioethicist with extensive clinical and research experience. I am the author of 41 peer-reviewed articles, which have been published in high-impact journals including the *Journal of the American Medical Association* and *Annals of Internal Medicine*, and I direct the Ethics Center at Cincinnati Children's Hospital Medical Center. I have reviewed the ban and submit this declaration to explain my disagreement with and concerns about many of the assertions offered in its support.

5. The ban, singles out gender transition procedures, which I will refer to as gender-affirming medical care, for anomalous treatment, prohibiting healthcare professionals from providing gender-affirming medical care to minors.

6. The ban holds gender-affirming medical care for adolescents with gender dysphoria to a standard that many accepted medical treatments do not attain. The evidence for gender-affirming care is comparable to the evidence for many other treatments in pediatrics. The legislative findings also mischaracterize the potential benefits and risks of gender-affirming medical care and fail to demonstrate that parents or legal guardians are incapable of providing informed consent for this medical care for their minor adolescents.

7. As a result, the ban puts clinicians in the untenable position of either following state law and violating their ethical duties to promote their patients' well-being and protect them from harm, or facing professional discipline, including permanent revocation of their licenses, and other potential penalties. Either outcome results in harm to patients.

BACKGROUND AND QUALIFICATIONS

8. I am the Director of the Ethics Center, the Lee Ault Carter Chair of Pediatric Ethics, and an Attending Physician in the Division of Hospital Medicine at Cincinnati Children's Hospital

Medical Center ("Cincinnati Children's"). I am also a Professor in the Departments of Pediatrics and Surgery at the University of Cincinnati College of Medicine.

9. I received my medical degree from Washington University School of Medicine in St. Louis, Missouri in 2000. I received my PhD in Religious Ethics from The University of Chicago Divinity School in 2000. I completed my pediatrics residency at the University of Utah in 2003.

10. I have been licensed to practice medicine since 2001 and am currently licensed to practice medicine in Ohio. I have been Board Certified in General Pediatrics since 2004 and in Pediatric Hospital Medicine since the inception of this certification in 2019. I have been certified as a Healthcare Ethics Consultant since the inception of this certification in 2019.

11. I have extensive experience as a pediatrician and as a bioethicist. I have been in clinical practice since 2003 and 30% of my current effort is dedicated to caring for hospitalized patients. I was Chair of the Ethics Committee at Primary Children's Medical Center in Salt Lake City, Utah from 2005 to 2012 and have been Director of the Ethics Center at Cincinnati Children's since 2012. I regularly consult on the care of patients in the Transgender Health Clinic at Cincinnati Children's and participate in the Clinic's monthly multidisciplinary team meetings. I remain current with the medical and bioethics literature regarding the treatment of minors with gender dysphoria. I am also part of Cincinnati Children's team that cares for patients born with differences or disorders of sex development (DSD), also known as intersex traits. I chair Cincinnati Children's Fetal Care Center's Oversight Committee, which provides the Center recommendations on the use of innovative treatments and experimental interventions.

12. I am a member of the American Academy of Pediatrics (AAP), the American Society for Bioethics and Humanities (ASBH), the Association of Bioethics Program Directors, and the Society for Pediatric Research. I was a member of the AAP Committee on Bioethics from

2005 to 2011. I have also served as a member of ASBH's Clinical Ethics Consultation Affairs Committee from 2009 to 2014 and currently serve on its Healthcare Ethics Consultant Certification Commission.

13. I am the author of 41 peer-reviewed journal articles, 11 non-peer-reviewed journal articles, 6 book chapters, and 28 commentaries. My peer-reviewed journal articles have been published in high-impact journals, including the *Journal of the American Medical Association* and *Annals of Internal Medicine.* I am also an author of 17 policy statements and technical reports, including 4 as lead author, by the AAP.

14. I am a member of the Executive Editorial Board and the Associate Editor for Ethics Rounds of *Pediatrics.* I am an active peer reviewer for many medical journals, including the *American Journal of Bioethics* and the *Journal of Pediatrics*. I also review abstracts for meetings of professional organizations, including the Pediatric Academic Societies and ASBH. I was previously a member of the editorial boards of the *Journal of Clinical Ethics* and the *Journal of Medical Humanities.*

15. I have previously testified at deposition and trial in *Dylan Brandt, et al., v. Leslie Rutledge, et al*., United States District Court, Eastern District of Arkansas, Case No. 5:21-CV-00450-JM-1; and at deposition in *August Dekker, et al., v. Jason Weida, et al*., United States District Court, Northern District of Florida, Case No. 4:22-cv-00325-RH-MAF. I have also previously testified in the preliminary injunction phase in the following matters: *Jane Doe, et al., v. Greg Abbott, et al.*, District Court of Travis County, Texas 353rd Judicial District, Case No. D-1-GN-22-000977; and *Brianna Boe, et al., and United States v. Marshall, et al.*, United States District Court, Middle District of Alabama Northern Division, Case No. 22-cv-184-LCB-CWB. I am being compensated at an hourly rate of $250 per hour for preparation of expert declarations

and reports, and $400 per hour for time spent preparing for or giving deposition or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

THE TREATMENT OF GENDER DYSPHORIA IS SUPPORTED BY EVIDENCE COMPARABLE TO THE EVIDENCE FOR MANY OTHER MEDICAL TREATMENTS

Clinical Practice Guidelines

16. Medical professional organizations develop clinical practice guidelines to provide clinicians with helpful, evidence-based recommendations and improve patient care and outcomes. Clinical practice guidelines are developed using systematic processes to select and review scientific evidence. Guidelines typically rate the quality of the evidence and grade the strength of recommendations.[1]

17. Clinical practice has different goals and methods from research or experimentation. Clinical practice's goal is to benefit individual patients and its method is individualized decision-making. Research's goal is to contribute to generalizable knowledge and research is conducted using formal protocols that describe its objectives and procedures.[2] For example, a research study may have restrictive inclusion and exclusion criteria for participants in order to increase the ability of the study to draw scientifically valid conclusions. A clinician may, however, recommend a treatment to a patient who would not have been eligible for the study because the clinician believes

[1] American Academy of Pediatrics Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874-77; Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

[2] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* The Commission; 1978.

the treatment will benefit the patient. The clinician will subsequently make recommendations about whether to modify or discontinue the treatment based on the patient's response to it.

18. In clinical practice guidelines, the quality of evidence has been defined as "the extent to which one can be confident that an estimate of effect is correct."[3] Quality of evidence is based on 4 factors: study design, study quality, consistency, and directness. The Grades of Recommendation Assessment, Development and Evaluation (GRADE) system, one widely used method of grading the quality of the evidence and the strength of recommendations, distinguishes 4 levels of evidence: "high," "moderate," "low," and "very-low." These levels are relative to one another and "low" does not necessarily mean poor or inadequate. As discussed below, a recommendation in a clinical practice guideline may be based on "low" or "very low" quality evidence, not just "high" or "moderate" quality evidence.[4]

19. With respect to study design, randomized trials generally provide "high" quality evidence.[5] In a randomized trial, participants are randomly assigned to a treatment or a comparison group. The major benefit of a randomized trial is that it decreases the likelihood that any

[3] Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.
[4] Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.
[5] Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

differences in the outcomes between the groups is the result of baseline differences between the groups rather than the result of the intervention.[6]

20. By comparison, observational studies generally constitute "low" quality evidence.[7] Observational studies include cross-sectional and longitudinal studies. In cross-sectional studies, investigators collect data at a single point in time. Cross-sectional design permits investigators to examine potential associations between factors, but it cannot prove one factor caused the other. An example of a cross-sectional study related to gender-affirming medical care is Jack L. Turban and colleagues' analysis of data from the 2015 United States (US) Transgender Survey. The survey asked transgender adults, who were recruited through community outreach, about their demographics, past gender-affirming medical care, family support, and mental health outcomes. The investigators found those who received pubertal suppression had lower odds of lifetime suicidal ideation compared to those who wanted treatment with pubertal suppression but did not receive it.[8] In longitudinal studies, researchers follow individuals over time, making continuous or repeated measures.[9] Examples of longitudinal studies include the studies of the associations between gender-affirming medical care and psychological outcomes discussed below.[10]

21. The labels "high" and "low" quality evidence can be misleading if the latter is used in the colloquial sense of poor or inadequate. While randomized controlled trials are described in

---

[6] Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2023.
[7] Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.
[8] Turban JL, King D, Carswell JM, Keuroghlian AS. Pubertal suppression for transgender youth and risk of suicidal ideation. *Pediatrics*. 2020;145(2):e20191725.
[9] Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2023.
[10] See, for example, de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex*

the medical literature as "high" quality evidence and observational studies as "low" quality evidence, randomized controlled trials may not be feasible or ethical, may have intrinsic methodological limitations, or may be unavailable in some contexts. "Low" quality evidence can be sufficient to justify treatment recommendations.[11]

22. At times, it may be unethical to conduct randomized trials. For randomized trials to be ethical, clinical equipoise must exist; there must be uncertainty about whether the efficacy of the intervention or the control is greater. Otherwise, it would be unethical to knowingly expose trial participants to an inferior intervention or control. Trials must also be feasible; it would also be unethical to expose individuals to the risks of trial participation without the benefit of the trial generating generalizable knowledge. A randomized trial that is unlikely to find enough people to participate because they believe they might be randomized to an inferior intervention would be unethical because it could not produce generalizable knowledge due to an inadequate sample size.[12]

23. Clinical research focusing on children is less likely to use randomized trials than is clinical research for adults. Potential reasons for this disparity include the low prevalence of childhood disease, small market share for therapeutic agents in children, low level of National Institutes of Health funding, and difficulty enrolling children in research.[13]

24. When making recommendations, the authors of guidelines consider a variety of

---

Med. 2011;8(8):2276-83.

[11] Swiglo BA, Murad MH, Schunemann HJ, et al. A case for clarity, consistency, and helpfulness: State-of-the-art clinical practice guidelines in endocrinology using the Grading of Recommendations, Assessment, Development, and Evaluation System. *J Clin Endocrinol Metab*. 2008;93(3):666-673.

[12] Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA*. 2000;283(20):2701-2711.

[13] Martinez-Castaldi C, Silverstein M, Baucher H. Child versus adult research: The gap in high

factors; the quality of the evidence is only one factor considered in making recommendations. Other considerations include the balance between desirable and undesirable outcomes, confidence and variability in patients' values and preferences, and resource use.[14] The GRADE system distinguishes "strong" and "weak" recommendations; if the authors are highly confident in the balance between desirable and undesirable consequences, they make a "strong" recommendation and, if they are less confident, a "weak" recommendation.[15] The larger the differences between the desirable and undesirable consequences and the lesser the variability in patient values and preferences, the more likely a "strong" recommendation is warranted. "Low" quality evidence may be sufficient to make a "strong" recommendation.[16]

25. Recommendations for pediatric care made by professional associations in guidelines are seldom based on well-designed and conducted randomized controlled trials due to their rarity. Instead, recommendations are frequently based on observational studies or, if such studies are unavailable, expert opinion. The medical use of the term "expert opinion" in this context refers to the consensus of experts when studies are not available.

26. For example, of the 130 recommendations in the American Heart Association's guideline for Pediatric Basic and Advanced Life Support, only 1 (0.8%) is based on "high-quality

---

quality study design. *Pediatrics*. 2008;122(1):52-57.

[14] Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490; Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.

[15] Andrews J, Guyatt G, Oxman AD, et al. GRADE guidelines: 14. Going from evidence to recommendations: The significance and presentation of recommendations. *J Clin Epidemiol*. 2013;66(7):719-725.

[16] Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.

evidence from more than 1 [randomized clinical trial]" and 3 (2.3%) on "moderate-quality evidence from 1 or more [randomized clinical trials]." The remainder of the recommendations were based on lower quality evidence. Among its 57 "strong" recommendations (both Class 1 and Class 3 Harm), 48 (84%) are based on "limited data" or "expert opinion."[17] Table 1 (Exhibit B).

Clinical Practice Guidelines for Gender-Affirming Medical Care for Minors

27. Gender-affirming medical care is not experimental; the level of evidence supporting clinical practice guidelines recommendations regarding gender-affirming medical care for adolescents is comparable to the level of evidence supporting many other pediatric medical treatments.

28. The ban's legislative findings characterize gender-affirming medical care for minors as "experimental" and "not supported by high-quality, long-term medical studies." 68-33-101(b). Gender-affirming care for minors is not experimental in the colloquial or technical senses. It is not new, novel, or unproven. The first reference to the use of puberty blockers for the treatment of gender dysphoria in the medical literature was in 1998, approximately 25 years ago.[18] Prospective observational trials of puberty blockers began recruiting participants in 2000.[19] Evidence for this this medical care will be discussed in greater detail below. Gender-affirming

[17] Topjian AA, Raymond TT, Atkins D, et al. Part 4: Pediatric basic and advanced life support: 2020 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2020;142(16_suppl_2):S469-S523. These clinical practice guidelines use different terminology than the GRADE approach for describing the quality of the evidence and the strength of recommendations.

[18] Cohen-Kettenis PT, van Goozen SH. Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent. *Eur Child Adolesc Psychiatry*. 1998;7(4):246-248. See also Gooren L, Delemarre-van de Waal H. The feasibility of endocrine interventions in juvenile transsexuals. *J Psychol Human Sex*. 1996;8(4):69-74.

[19] de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283.

medical care is also not experimental in the technical sense; it is intended to benefit individual patients and is modified based on individual patients' responses.[20]

29. The Endocrine Society, an international medical organization of over 18,000 endocrinology researchers and clinicians, has published a clinical practice guideline for the treatment of gender-dysphoric/gender-incongruent persons, including pubertal suppression, sex hormone treatment, and surgery for gender confirmation.[21] Gender-affirming medical care is also recommended by the World Professional Association for Transgender Health's (WPATH's) Standards of Care for the Health of Transgender and Gender Diverse People which is currently in its 8th version ("SOC-8").[22] The treatments outlined in these guidelines are also endorsed by other medical professional associations including the American Academy of Family Physicians,[23] the AAP,[24] the American College of Obstetricians and Gynecologists,[25] the American Medical

[20] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. The Commission; 1978.

[21] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

[22] Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, Version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S1-S259.

[23] American Academy of Family Physicians. Care for the transgender and gender nonbinary patient. Accessed January 8, 2023. Available at https://www.aafp.org/about/policies/all/transgender-nonbinary.html#:~:text=The%20American%20Academy%20of%20Family,patients%2C%20including%20children%20and%20adolescents.

[24] Rafferty J, Committee on Psychosocial Aspects of Child and Family Health, Committee on Adolescence, et al. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. *Pediatrics*. 2018;142(4): e20182162.

[25] American College of Obstetricians and Gynecologists. ACOG Committee Opinion Number 823: Health care for transgender and gender diverse individuals. March 2021. Accessed January 8, 2023. Available at https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals/; American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice and Committee on Health Care for Underserved Women. Health care for transgender and gender diverse

Association,[26] the APA,[27] the American Psychological Association (APA),[28] and the Pediatric Endocrine Society.[29]

30. The Endocrine Society clinical practice guideline includes 28 recommendations: 3 (11%) are based on "moderate," and 19 (68%) are based on "low" or "very low" quality evidence. The remaining 6 (21%) recommendations are Ungraded Good Practice Statements.[30] Table 2 (Exhibit C).

31. The quality of the evidence supporting these recommendations is similar to the quality of the evidence supporting the recommendations in other Endocrine Society clinical practice guidelines for the pediatric population. For example, none of the Endocrine Society's 84 recommendations in its 2 other guidelines that focus on the pediatric population—guidelines on pediatric obesity and congenital adrenal hyperplasia—is based on "high" quality evidence.

---

individuals: ACOG Committee Opinion, Number 823. *Obstet Gynecol*. 2021;137(3):e75-e88.

[26] American Medical Association. Removing financial barriers to care for transgender patients H-185.950. 2022. Accessed January 8, 2023. Available at https://policysearch.ama-assn.org/policyfinder/detail/H-185.950?uri=%2FAMADoc%2FHOD.xml-0-1128.xml; Madara JL to McBride B. April 26, 2021. Accessed January 8, 2023. Available at https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-4-26-Bill-McBride-opposing-anti-trans-bills-Final.pdf.

[27] American Psychiatric Association. Position statement on treatment of transgender (trans) and gender diverse youth. July 2020. Accessed January 8, 2023. Available at https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Policies/Position-Transgender-Gender-Diverse-Youth.pdf.

[28] American Psychological Association. Transgender, gender identity, and gender expression non-discrimination. August 2008. Accessed January 8, 2023, Available at https://www.apa.org/about/policy/transgender.pdf.

[29] Endocrine Society and Pediatric Endocrine Society. Transgender health: Position Statement. December 2020. Accessed January 8, 2023. Available at https://www.endocrine.org/advocacy/position-statements/transgender-health; Anton BS. Proceedings of the American Psychological Association for the legislative year 2008: Minutes of the annual meeting of the Council of Representatives. *Am Psychol*. 2009;64:372-453.

[30] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

Twenty-four (29%) of the recommendations are based on "moderate," and 49 (58%) on "low" or "very low" quality evidence. The remaining recommendations (11, 13%) are Ungraded Good Practice Statements.[31] Table 2 (Exhibit C).

32. With respect to puberty-delaying medication, the Endocrine Society specifically "suggest[s] that adolescents who meet diagnostic criteria for [gender dysphoria]/gender incongruence, fulfill criteria for treatment, . . . and are requesting treatment should initially undergo treatment to suppress pubertal development."[32] The evidence for this recommendation includes a longitudinal study of a group of 70 transgender adolescents who were evaluated using objective measures prior to both pubertal suppression and sex hormone treatment. The mean length of time between the start of pubertal suppression and sex hormone treatment was 1.88 years and ranged from 0.42 to 5.06 years. The study showed statistically significant decreases in behavioral and emotional problems and depressive symptoms, and increases in general functioning.[33]

33. This is the same level of evidence as supports the use of puberty blockers for the treatment of central precocious puberty which the ban permits. Central precocious puberty is the premature initiation of puberty, before 8 years of age in people assigned female at birth and before 9 in people assigned male, by the central nervous system. The potential negative effects of

[31] Speiser PW, Arlt W, Auchus RJ, et al. Congenital adrenal hyperplasia due to steroid 21-hydroxylase deficiency: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2018;103(11):4043-4088; Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesity-assessment, treatment, and prevention: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(3):709-757.

[32] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

[33] See de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283.

precocious puberty can include impairment of final adult height as well as antisocial behavior and lower academic achievement. There are no randomized trials evaluating the adult height of treated and untreated individuals. Most studies are observational and compare pretreatment predicted final height with actual final height. These studies have additional limitations including small sample sizes. This "low" quality evidence nonetheless is sufficient to support the use of GnRH agonists as treatment for central precocious puberty.[34] The ban therefore subjects the use of puberty blockers to a double standard. There are no randomized clinical trials for the use of puberty blockers to treat precocious puberty or gender dysphoria, but the evidence is deemed sufficient for the former but not the latter.

34. The evidence supporting the guideline's recommendations regarding gender-affirming hormone treatment in adolescents include Cohen-Kettenis and colleagues' longer-term follow-up of individuals after pubertal suppression through sex hormone and gender-affirming surgical treatment. Participants' mean age at their initial assessment was 13.6 years and their mean age at their final assessment was 20.7 years. The researchers report the resolution of gender dysphoria and improvement in psychological functioning.[35]

35. As a result of these studies and healthcare providers' subsequent experience, randomized, placebo-controlled trials (trials that compare pharmacological treatment to no

[34] Mul D, Hughes IA. The use of GnRH agonists in precocious puberty. *Eur J Endocrinol*. 2008;159 Suppl 1:S3-8.
[35] See de Vries AL, McGuire JK, Steensma TD, Wagenaar EC, Doreleijers TA, Cohen-Kettenis PT. Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics*. 2014;134(4):696-704. Additional longitudinal studies of the psychosocial effects of pubertal suppression to treat gender dysphoria include Costa R, Dunsford M, Skagerberg E, Holt V, Carmichael P, Colizzi M. Psychological support, puberty suppression, and psychosocial functioning in adolescents with gender dysphoria. *J Sex Med.* 2015;12(11):2206-2214 and Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12- to 15-year old young people with persistent gender dysphoria in the UK. *PLoS One.* 2021;16(2):e0243894.

pharmacological treatment) of gender-affirming medical care are currently unethical. Potential investigators do not have equipoise between pharmacological treatment and no pharmacological treatment; they believe that pharmacological treatment is superior. It is also highly unlikely that a sufficient number of participants would enroll in randomized controlled trials for them to be informative.[36]

36. Even if such studies could be conducted ethically, they would provide a lower quality of evidence because of intrinsic limitations in their design. For example, it would be impossible to blind the investigators or the participants to whether the participants were receiving the active treatment or a placebo. They would know if participants were in the intervention or other control arm of the study due to the physical changes in their bodies, or the lack thereof, over time. This might bias their perception of the outcomes and lower the rating of the study's quality.[37]

GENERALLY APPLICABLE PRINCIPLES OF INFORMED CONSENT APPLY TO PEDIATRIC GENDER-AFFIRMING MEDICAL CARE

37. Before performing any medical intervention, a healthcare provider must generally obtain an adult patient's informed consent. Informed consent is a process in which the provider discloses information, elicits the patient's preferences, offers medical advice, and seeks explicit authorization. In order to participate in the informed consent process, a patient must have medical decision-making capacity. If an adult patient lacks capacity, a proxy decision maker is generally appointed. The healthcare provider's disclosure should include the nature of the intervention and

[36] Chew D, Anderson J, Williams K, May T, Pang K. Hormonal treatment in young people with gender dysphoria: A systematic review. *Pediatrics*. 2018;141(4):e20173742; Reisner SL, Deutsch MB, Bhasin S, et al. Advancing methods for US transgender health research. *Curr Opin Endocrinol Diabetes Obes*. 2016;23(2):198-207.

[37] Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2023; Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

the reasons for it, as well as its potential benefits, risks, and alternatives, including the alternative of not undergoing the intervention. The patient or the patient's proxy must understand and appreciate this information and express a decision. For the informed consent to be valid, the authorization must be voluntary. Exceptions to the requirement to obtain informed consent exist, such as in the case of an emergency.[38]

38. Medical decision-making and informed consent in pediatrics is more complex than in adult medicine because it involves both minor patients and their parents or legal guardians. Parents and guardians are afforded substantial, but not unlimited, discretion in making medical decisions for their minor children based on their assessment of the individual child's best interest. They generally care about their children and best understand their children's unique needs.[39]

39. Healthcare providers also have an ethical obligation to include children in medical decision-making to the extent that it is developmentally appropriate. For example, a provider examining a toddler for a possible ear infection should not ask a toddler for permission to look in the child's ear because the provider intends to look even if the child says no. The provider could, however, ask the toddler which ear the child would like to have looked in first. As a minor becomes older, the minor should participate more actively in medical decision-making and the minor's assent should be sought. In early adolescence, individuals typically have developed a sense of identity, individual values and preferences, and are developing medical decision-making capacity. Capacity entails the ability to (i) understand the indications and the potential benefits, risks, and alternatives to a treatment, including declining treatment; (ii) appreciate the implications of a

[38] Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 6th ed. Oxford University Press; 2009.
[39] Diekema DS. Parental refusals of medical treatment: The harm principle as threshold for state intervention. *Theor Med Bioeth.* 2004;25(4):243-264.

treatment decision for their own lives; (iii) evaluate the potential benefits and risks; and (iv) express a preference.[40]

40. The current treatment paradigm for treating gender dysphoria in minors is consistent with general ethical principles instantiated in the practices of informed consent and assent. The Endocrine Society clinical practice guideline extensively discusses the potential benefits, risks, and alternatives to treatment, and its recommendations regarding the timing of interventions are based in part on the treatment's potential risks and the adolescent's decision-making capacity. The guideline recommends that the informed consent process for puberty blockers and sex hormones include a discussion of the implications for fertility and options for fertility preservation. The Endocrine Society clinical practice guideline also advises delaying gender-affirming hormone treatment, which results in partly irreversible physical changes, until an adolescent is developmentally capable of providing informed consent.[41]

THE BAN MISCHARACTERIZES GENDER-AFFIRMING MEDICAL CARE, INCLUDING ITS BENEFITS, RISKS, AND ALTERNATIVES

41. The ban's legislative findings inaccurately characterize gender-affirming medical care in several different ways. The legislative findings, for example, dismiss the potential medical benefits of gender-affirming care, exaggerate its potential risks, and ignore the substantial risks of failing to provide adequate treatment. The legislative findings also do not explain why parents or guardians should have their decision-making authority substituted by the government's with respect to gender-affirming medical care.

---

[40] Katz AL, Webb SA, Committee on Bioethics. Informed consent in decision-making in pediatric practice. *Pediatrics*. 2016;138(2):e20161485; Kon AA, Morrison W. Shared decision-making in pediatric practice: A broad view. *Pediatrics*. 2018;142(Suppl 3):S129-S132.

[41] See Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

The Ban Disregards the Benefits of Gender-Affirming Care

42. While the ban refers to medical procedures "performed for the purpose of enabling a minor to identify with, or live as, a purported identity inconsistent with the minor's sex or treating purported discomfort or distress from a discordance between the minor's sex and asserted identity," 68-33-101, it is important to note that gender-affirming medical care is treatment for a serious medical condition - gender dysphoria. Gender dysphoria is a medical diagnosis contained in the APA's Diagnostic and Statistical Manual of Mental Disorders, 5th ed, Text Revision. It is "a marked incongruence between one's experienced/expressed gender and their assigned gender" which is "associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning."[42]

43. The potential benefits of gender-affirming medical care include improved physical and psychological outcomes. Starting pubertal suppression in early puberty prevents adolescents with gender dysphoria from developing secondary sex characteristics inconsistent with their gender identity, which can be extremely distressing for them, and that may be difficult, if not impossible, to eliminate once the characteristics have fully developed. Sex hormone therapy results in the development of secondary sex characteristics consistent with individuals' gender identity. Potential psychological benefits include increased quality of life and decreased depression, suicidal ideation and suicide attempts, and anxiety.[43]

[42] American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed, Text Revision. American Psychiatric Publishing; 2022.
[43] See, for example, Baker KE, Wilson LM, Sharma R, Dukhanin V, McArthur K, Robinson KA. Hormone therapy, mental health, and quality of life among transgender people: A systematic review. *J Endocr Soc*. 2021;5(4):1-16.

The Ban Exaggerates the Risks of Gender-Affirming Medical Care

44. The legislative findings state that gender-affirming care for adolescents "can lead to the minor becoming irreversibly sterile, having increased risk of disease and illness, or suffering from adverse and sometimes fatal psychological consequences" and that "it likely that not all harmful effects associated with these types of medical procedures when performed on a minor are yet fully known." 68-33-101(b). As with all medical treatments, gender-affirming medical care entails risks. But the legislative findings exaggerate its potential risks and attribute harms to it without any empirical support. The fact that gender-affirming medical care has risks does not distinguish it from other forms of treatment.

45. The findings overstate the potential effects of gender-affirming care on fertility. Puberty blockers do not, by themselves, permanently impair fertility. Children with central precocious puberty are routinely treated with puberty blockers and have typical fertility in adulthood.[44] These medications are also used for fertility preservation in individuals being treated for cancer.[45]

46. While treatment for gender dysphoria with gender-affirming hormones may impair fertility, this is not universal and may also be reversible. There are transgender men who became pregnant while on or after discontinuing testosterone therapy.[46] Transgender men and women are

[44] Lazar L, Meyerovitch J, de Vries L, Phillip M, Lebenthal Y. Treated and untreated women with idiopathic precocious puberty: Long-term follow-up and reproductive outcome between the third and fifth decades. *Clin Endocrinol* (Oxf). 2014;80(4):570-576.
[45] Valsamakis G, Valtetsiotis K, Charmandari E, Lambrinoudaki I, Vlahos NF. GnRH analogues as a co-treatment to therapy in women of reproductive age with cancer and fertility preservation. *Int J Mol Sci*. 2022;23(4):2287.
[46] Light AD, Obedin-Maliver J, Sevelius JM, Kerns JL. Transgender men who experienced pregnancy after female-to-male gender transitioning. *Obstet Gynecol*. 2014;124(6):1120-1127.

also capable of producing eggs and sperm respectively both during and after the discontinuation of gender-affirming hormone treatment.[47]

47. Additionally, offering individuals considering gender-affirming medical care methods to potentially preserve their fertility is a component of the clinical practice guidelines discussed above.[48]

48. The risk of infertility is also not unique to treatment for gender dysphoria. For example, parents and legal guardians consent to the treatment of nonmalignant medical conditions for their minor children, including some rheumatologic disorders and hematologic conditions, which may impair fertility.[49]

49. The legislative findings also state that providing gender-affirming care for minors leads to an "increased risk of disease and illness, or suffering from adverse and sometimes fatal psychological consequences." 68-33-101(b). While transgender adolescents have higher rates of depression, anxiety, suicidal ideation, and suicide attempts, there are no studies indicating that those higher rates are caused by, or exacerbated by, providing gender-affirming medical care.[50] Rather, contributing factors include conflict between one's appearance and identity, stigma, and

[47] Leung A, Sakkas D, Pang S, Thornton K, Resetkova N. Assisted reproductive technology outcomes in female-to-male transgender patients compared with cisgender patients: A new frontier in reproductive medicine. *Fertil Steril.* 2019;112(5):858-865; de Nie I, van Mello NM, Vlahakis E, et al. Successful restoration of spermatogenesis following gender-affirming hormone therapy in transgender women. *Cell Rep Med*. 2023;4(1):100858.

[48] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

[49] Hirshfeld-Cytron J, Gracia C, Woodruff TK. Nonmalignant diseases and treatments associated with primary ovarian failure: An expanded role for fertility preservation. *J Womens Health (Larchmt)*. 2011;20(10):1467-1477.

[50] Haas AP, Eliason M, Mays VM, et al. Suicide and suicide risk in lesbian, gay, bisexual, and transgender populations: Review and recommendations. *J Homosex.* 2011;58(1):10-51.

rejection.[51] As discussed above, the available evidence indicates that gender-affirming care improves, rather than worsens, psychological outcomes.

50. Finally, not knowing all potential harmful effects associated with a medication is not a sufficient reason for the United States Food and Drug Administration (FDA) to not approve a medication, let alone a state to ban it. The FDA requires post-marketing surveillance of medications' adverse effects because the clinical trials on which the approvals are based cannot identity all possible side effects.[52]

The Ban Ignores the Risks of Harm From Lack of Treatment

51. In determining whether the benefits of treatment outweigh the risks, medical providers and patients must also consider the risks of failing to provide treatment. As stated above, prior to the initiation of gender-affirming medical care, many individuals with gender dysphoria have significant, unresolved symptoms that treatment improves. Without medical treatment, these symptoms would persist.

52. While the medical care ban's legislative findings assert "a minor's discordance can be resolved by less invasive approaches that are likely to result in better outcomes for the minor," 68-33-101(c), I am unaware of such approaches or any evidence supporting such claim.

The Risks and Benefits of Gender-Affirming Medical Care are Comparable to Those of Other Medical Care to which Parents and Guardians May Consent

53. Medical care for minors can require weighing potential benefits and risks in the face of uncertainty. There is nothing unique about gender-affirming medical care that justifies

[51] Bauer GR, Scheim AI, Pyne J, Travers R, Hammond R. Intervenable factors associated with suicide risk in transgender persons: A respondent driven sampling study in Ontario, Canada. *BMC Public Health*. 2015;15:525.
[52] U.S. Food & Drug Administration. Postmarketing Surveillance Programs. April 2, 2020. Accessed February 26, 2023. Available at https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs.

singling out this medical care for prohibition based on concern for adolescents' inability to assent or parents or guardians' inability to consent. Medical decisions regarding treatment for gender dysphoria should continue to be left to the discretion of adolescents, their parents or guardians, and their healthcare providers.

54. The potential risks of gender affirming medical care are comparable to the risks parents and adolescents are permitted to assume in numerous other treatment decisions, including decisions explicitly authorized by this legislation. Parents of children with some types of malignancies may choose treatments that may damage their children's gonads and result in infertility.[53] Individuals with some types of DSDs, such as complete androgen insensitivity syndrome, are treated with sex hormones, which have comparable risks to the use of these treatments in persons with gender dysphoria.[54] And, parents of children with some types of DSDs may choose to have their children's gonads removed due to the possible elevated risk of malignancy, which causes infertility.[55] It is also my understanding that the medical care ban permits gender-affirming medical treatment of individuals with DSDs, which has similar risks to the use of this treatment in individuals who do not have DSDs. The types of risks present for breast reduction surgery, which may be performed for cosmetic reasons or to reduce physical discomfort, are similar to those of chest surgery to treat gender dysphoria.[56]

---

[53] Delessard M, Saulnier J, Rives A, Dumont L, Rondanino C, Rives N. Exposure to chemotherapy during childhood or adulthood and consequences on spermatogenesis and male fertility. *Int J Mol Sci*. 2020;21(4):1454; Blumenfeld Z. Chemotherapy and fertility. *Best Pract Res Clin Obstet Gynaecol*. 2012;26(3):379-390.

[54] Lanciotti L, Cofini M, Leonardi A, Bertozzi M, Penta L, Esposito S. Different clinical presentations and management in complete androgen insensitivity syndrome (CAIS). *Int J Environ Res Public Health*. 2019;16(7):2168.

[55] Abaci A, Catli G, Berberoglu M. Gonadal malignancy risk and prophylactic gonadectomy in disorders of sexual development. *J Pediatr Endocrinol Metab*. 2015;28(9-10):1019-1027.

[56] Manahan MA, Buretta KJ, Chang D, Mithani SK, Mallalieu J, Shermak MA. An outcomes analysis of 2142 breast reduction procedures. *Ann Plast Surg*. 2015;74(3):289-292.

Legislative Findings About Regret Do Not Support a Ban

55. The legislative findings state, "many individuals have expressed regret for medical procedures that were performed on or administered to them for such purposes when they were minors." 68-33-101(g). The experience of regret as a result of any medical treatment is profoundly unfortunate, and individuals experiencing regret should be provided support and any additional treatment needed.

56. While there have been anecdotal reports of regret, the available studies report that rates of regret are very low. For example, Chantal M. Wiepjes and colleagues report that 0.6% of transgender women and 0.3% of transgender men who had their gonads removed experienced regret.[57] Similarly, R. Hall and colleagues report regret was specifically documented in 1.1% of adult gender-diverse patients.[58] Banning gender-affirming medical care to prevent regret in a small minority of patients would result in harm to the majority of patients who benefit. Support and services should nonetheless be provided to individuals who experience regret.

57. The potential for regret is also not unique to gender-affirming medical care. Ironically, at the same time that Tennessee prohibits gender-affirming medical care for minors in the name of protecting vulnerable children, the statute expressly allows doctors to perform these irreversible genital surgeries on infants and children with DSDs at ages when they are unable to meaningfully participate in medical decision-making. The evidence base for these surgeries is poor

[57] Wiepjes CM, Nota NM, de Blok CJM, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in prevalence, treatment, and regrets. *J Sex Med*. Apr 2018;15(4):582-590.
[58] Hall R, Mitchell L, Sachdeva J. Access to care and frequency of detransition among a cohort discharged by a UK national adult gender identity clinic: Retrospective case-note review. *BJPsych Open*. 2021;7(6):e184.

and they are highly controversial when performed at such an early age.[59] Parents of children who have undergone feminizing genitoplasty and hypospadias repair have experienced regret for their decisions.[60] For example, Rachel S. Fisher and colleagues found that 38% of caregivers of infants with congenital adrenal hyperplasia reported some level of regret about their child's genital surgery.

The Increased Prevalence of Gender-Affirming Care Does Not Support a Ban

58. The legislative findings state that the gender-affirming medical care is being provided "with rapidly increasing frequency." 68-33-101(g). The increased number of transgender individuals and those receiving medical treatment is likely to be multifactorial including increased social acceptance of transgender individuals and availability of gender-affirming medical care.[61] Changes in demographics are not unique to gender dysphoria and have been seen in other conditions such as autism spectrum disorder and childhood-onset type 1 diabetes.[62] These changes are a justification for further research on gender-affirming medical care rather than prohibiting these treatments and thereby preventing further research on them.

---

[59] Jesus LE. Feminizing genioplasties: Where are we now? *J Pediatr Urol*. 2018;14(5):407-415; Frader J, Alderson P, Asch A, et al. Health care professionals and intersex conditions. *Arch Pediatr Adolesc Med*. 2004;158(5):426-428.

[60] Fisher RS, Espeleta HC, Baskin LS, et al. Decisional regret about surgical and non-surgical issues after genitoplasty among caregivers of female infants with CAH. *J Pediatr Urol*. 2022;18(1):27-33; Vavilov S, Smith G, Starkey M, Pockney P, Deshpande AV. Parental decision regret in childhood hypospadias surgery: A systematic review. *J Paediatr Child Health*. 2020;56(10):1514-1520.

[61] Wiepjes CM, Nota NM, de Blok CJM, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in prevalence, treatment, and regrets. *J Sex Med*. 2018;15(4):582-590.

[62] Christensen DL, Maenner MJ, Bilder D, et al. Prevalence and characteristics of autism spectrum disorder among children aged 4 years - Early Autism and Developmental Disabilities Monitoring Network, seven sites, United States, 2010, 2012, and 2014. *MMWR Surveill Summ*. 2019;68(2):1-19; The DIAMOND Project Group. Incidence and trends of childhood Type 1 diabetes worldwide 1990-1999. *Diabet Med*. 2006;23(8):857-866.

Treatment Protocols in Europe Do Not Support a Ban

59. The legislative findings also point to the actions of health authorities in Sweden, Finland, and the United Kingdom as support for the state's decision to ban gender-affirming medical care.[63] It is difficult to evaluate the actions of the Swedish and Finnish health authorities because all of the relevant material is not available in official English translations. The legislative findings characterize the authorities as conducting systematic reviews of the evidence and finding no evidence that the benefits of these procedures outweigh the risks. 68-33-101(e). This claim confuses systematic reviews of the literature and clinical practice guidelines. While both ideally grade the quality of the evidence, only clinical practice guidelines make recommendations and grade their strength. Of the documents by European health authorities that do make treatment recommendations, none rate the quality of the evidence and the strength of the recommendations.

60. Critically, none of the European health authorities has prohibited gender-affirming medical care as does Tennessee. The authorities instead emphasize the importance of

[63] The relevant documents include the following: Socialstyrelsen. God vård av barn och ungdomar med könsdysfori. March 2021. Accessed November 23, 2022. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2015-4-6.pdf; Socialstyrelsen. Stöd, utredning och hormonbehandling vid könsinkongruens hos barn och ungdomar. February 2022. Accessed November 23, 2022. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-2-7774.pdf; Socialstyrelsen: The National Board of Health and Welfare. Care of children and adolescents with gender dysphoria: Summary. Accessed November 23, 2022. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-3-7799.pdf; Palveluvalikoima. Medical treatment methods for dysphoria associated with variations in gender identity in minors – recommendations. June 16, 2020. Accessed November 23, 2022. Available at https://palveluvalikoima.fi/documents/1237350/22895008/Summary_minors_en+(1).pdf/fa2054c5-8c35-8492-59d6-b3de1c00de49/Summary_minors_en+(1).pdf?t=1631773838474; The Cass Review. Independent review of gender identity services for children and young people: Interim report. February 2022. Accessed November 23, 2022. Available at https://cass.independent-review.uk/publications/interim-report/.

multidisciplinary evaluation and treatment, including psychological care, and the need for additional research. Even though Sweden has called for the provision of gender-affirming medical care within the research context, the Swedish National Board of Health and Welfare states that doing so "does not necessarily imply the use of randomized controlled trials,"[64] acknowledging that other study designs are appropriate to evaluate gender-affirming medical care. The European documents do not support the claims that gender-affirming medical care should be banned.

THE MEDICAL CARE BAN UNDERMINES THE INTEGRITY OF THE MEDICAL PROFESSION

61. The legislative findings state, "[t]his state has a legitimate, substantial, and compelling interest in protecting the integrity of the medical profession," 68-33-101(m), when in fact the ban violates the integrity of the medical profession and coerces medical professionals to violate their integrity and ethical duties.

62. The medical profession has processes by which it evaluates treatments and determines whether they are safe and effective. The ban intervenes in these processes replacing medical professionals judgement with the judgment of the legislature. The ban itself violates the integrity of the medical profession by defining a disease, gender dysphoria, as not a disease. 68-33-103(b)(2). Gender-affirming medical care is in fact "consistent with professional medical standards," 68-33-101(c), and, as described above, it is endorsed by many medical professional associations.

63. Healthcare providers have an ethical obligation to promote their patients' well-being and to protect them from harm. When providers believe that the potential benefits of gender-

[64] Socialstyrelsen. Stöd, utredning och hormonbehandling vid könsinkongruens hos barn och ungdomar. February 2022. Accessed November 23, 2022. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-2-7774.pdf.

affirming medical care outweigh the potential risks for a particular patient, prohibiting them from providing this treatment forces them to violate their ethical obligations to their patients or risk losing their licenses and incurring financial penalties.

CONCLUSION

64. Treating adolescents with gender dysphoria with gender-affirming medical care under clinical practice guidelines, like the Endocrine Society's, is evidence-based; its potential benefits outweigh its potential risks for many patients; and these risks are well within the range of other medical decisions that adolescents and their parents or guardians have the discretion to make in consultation with their healthcare professionals.

65. Based on my research and experience as a pediatrician and bioethicist, there is no sound medical or ethical basis to prohibit healthcare professionals from providing gender-affirming medical care to minors. Doing so puts clinicians in the untenable position of having to harm their patients and violate their integrity and ethical obligations due to the threat of losing their licenses and incurring economic penalties.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: April 13, 2023

ARMAND H. MATHENY ANTOMMARIA, MD, PhD